

## **REMARKS / ARGUMENTS**

In response to the Office Action of February 7, 2008, Applicant has amended the claims, which when considered with the following remarks, is deemed to place the present application in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

Claims 11-20 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. On page 3 of the office action, the Examiner has asserted that the phrase “devoid of a hydrophilic phase” allegedly does not find support in the specification. Solely to advance prosecution of this application, and not in any way acquiescing to the position of the Examiner, claims 11 and 17 have been amended so that they no longer recite “devoid of a hydrophilic phase.” In view of the amendments to claims 11 and 17, withdrawal of the rejection of claims 11-20 under the written description provision of 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 17 and 18 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As discussed above claim 17 no longer recites “devoid of a hydrophilic phase.” Withdrawal of the rejection of claims 17 and 18 under 35 U.S.C. § 112, second paragraph, is therefore warranted.

Claims 11-19 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Posanski (GB 2 228 198A). Posanski has been cited for allegedly

teaching pharmaceutical compositions containing cyclosporin, a carrier composition that contains oils, a tenside having an HLB of 10 and Cremophor. The Examiner has further asserted that on page 10, line 4, Posanski describes the compositions as not being aqueous and that the amounts in the examples meet the amounts in the claims.

Applicant respectfully traverses the rejection for the following reasons. By this amendment, claims 11 and 17 recite “consisting of” rather than “consisting essentially of.” Support for the amendments to claims 11 and 17 may be found throughout the specification, e.g., page 2, lines 9-27. The carrier medium of Posanski comprises (b) a fatty acid triglyceride, (c) a glycerol fatty acid partial ester or propylene glycol (e.g. 1,2-propylene glycol) or sorbitol complete or partial ester, and (d) a tenside having a hydrophilic-lipophilic balance (HLB) of at least 10. See Posanski, page 11.

In contrast, claim 11 as presently amended recites a carrier composition consisting of:

a) about 10-50% by weight, based on the carrier composition, of a sorbitan fatty acid ester co-surfactant which is substantially pure or which is in the form of a mixture, having a hydrophilic-lipophilic balance of less than 10 (HLB value according to Griffin);

b) about 5-40% by weight, based on the carrier composition, of a pharmaceutically acceptable oil which is substantially pure or which is in the form of a mixture, comprising a triglyceride as essential lipophilic component; and

c) about 10-50% by weight, based on the carrier composition, of a nonionic surfactant which is substantially pure or which is in the form of a mixture, having an HLB value of more than 10; and further optional pharmaceutically acceptable excipients.

Examples of suitable sorbitan fatty acid esters for use in the present application include, e.g., sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, sorbitan sesquioleate and sorbitan trioleate, all of which have an HLB or less than 10, and none of which are taught by Posanski. See specification of the present application, page 7, as well as Table 16 of US Patent No. 6,923,988, provided herewith as Exhibit A. Since Posanski does not teach the composition of claims 11-19, withdrawal of the rejection of these claims under 35 U.S.C. §102(b) is respectfully requested.

Claims 19 and 20 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Posanski (GB 2 228 198 A). Applicant respectfully traverses the rejection for the following reasons. There is no suggestion in Posanski that the presently claimed formulation as presently recited in claim 11 could or should be made. Since there is no suggestion in Posanski et al. that the composition recited in claim 11 could or should be made, one skilled in the art at the time the invention was made, would not have found it obvious to practice the process of claims 19 and 20. Withdrawal of the rejection of claims 19 and 20 under 35 U.S.C. § 103(a) is therefore warranted.

Claims 11-20 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Cavanak (US Patent No. 5,639,724). Cavanak has been cited for allegedly teaching a composition containing cyclosporin as the active ingredient, glycerol fatty acid ester and a tenside having an HLB of 10. The Examiner has asserted that Cavanak describes a variety of cyclosporin compositions that contain sesame oil, Tween or Cremophor, triglyceride, neutral oils and diglycerides, Cremophor and sorbitan monolaurate and the process of combining the components into the formulation.

Applicant respectfully traverses the rejection for the following reasons. In the first instance, Cavanak does *not* teach or suggest sorbitan monolaurate at column 14, lines 43-67. Rather, Cavanak teaches polyoxyethylene-sorbitan-fatty acid esters, e.g., mono- and tri-lauryl, palmityl, stearyl and oleyl esters, e.g. of the type known and commercially available under the trade name Tween. Tween 40 and Tween 80 are especially preferred. Such polyoxyethylene-sorbitan-fatty acid esters in almost every case, have an HLB of greater than 10. See Table 11 of US Patent No. 6,923,988, provided herewith at Exhibit A. Thus, the polyoxyethylene (20) sorbitan monolaurate taught by Cavanak at column 14, line 49, is *not* the same as sorbitan monolaurate taught by Applicant at page 7, third full paragraph, of the specification. Indeed, the sorbitan fatty ester co-surfactants, recited in the claims and taught by the present application, e.g, sorbitan monolaurate, have an HLB of less than 10. See *also* Table 16 of US Patent No. 6,923,988, provided herewith at Exhibit A.

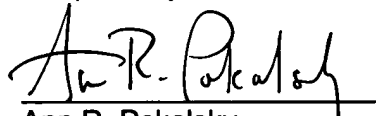
It is therefore respectfully submitted that at the time the invention was made, one skilled in the art having Cavanak in hand, would not have found it obvious to substitute a sorbitan fatty acid ester as presently claimed for a polyoxyethylene-sorbitan fatty acid ester taught by Cavanak. Thus, the presently claimed invention differs from Cavanak in more than just amounts and/or concentration of ingredients. Accordingly, withdrawal of the rejection of claims 11-20 under 35 U.S.C. § 103(a) is therefore respectfully requested.

Claims 11-20 have been rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1, 27-35 and 37; claims 1-10; and claims 1-10 of copending Application Nos. 11/453,504, 10/961,785 and 10/623,887, respectively. Applicant will consider filing a terminal disclaimer or else

demonstrate non-obviousness over the three cited applications upon allowance of the claims under consideration in this application. It is respectfully requested that the Examiner hold the double patenting rejection in abeyance until such time.

In view of the foregoing remarks and amendments, it is respectfully submitted that the pending claims are in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

  
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